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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,634	10/31/2001	Yongming Sun	DEX-0255	7580

26259 7590 07/20/2004

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EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 07/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,634	SUN ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,7-9 and 18-27* is/are pending in the application.

4a) Of the above claim(s) *19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,7-9,18 and 20-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Status of Claims

1. Claims 2,3, 6, 10-17 are canceled. Claims 18-27 are added. Claims 1,4,5,7-9,18-27 are pending.

Applicant added recitation of SEQ ID No. 18 in amended claim 1 and newly added claims 19,21-27. As the elected sequence is SEQ ID No. 19, and no "relation" of SEQ ID No. 18 to the SEQ ID No. 19 is demonstrated, claim 19 is withdrawn from consideration, and the remaining claims are addressed to the extent they read on SEQ ID No. 19.

Priority

2. Applicant submits that the provisional application 60/244758 provides adequate support for the claimed invention because SEQ ID No. 14 in 60/244758 is a "compliment or antisense" to instantly claimed SEQ ID No. 18, the latter being "related to SEQ ID No. 19". However, applicant does not explain what specific relation, being an antisense or complement, is attributed to the referenced sequence; nor what "relation" SEQ ID No. 18 has to SEQ ID No. 19. Priority is not granted to the provisional application, and the instant application is granted priority only to its filing date.

Claim Rejections - 35 USC § 112, second paragraph.

3. Claims 1,4,5,7-9,18,20-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1(d): It is not clear what is "entire length" for a nucleic acid molecule comprising nucleic acid molecule comprising sequence SEQ ID No.19 (i.e., according to the claim language that follows from reading preamble together with the following components of the claim). Consequently, the meaning and scope of language directed to "85% sequence identity to entire length" is not clear.

Claim Rejections - 35 USC § 112, first paragraph.

4. Claims 1,4,5,7-9,18,20-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The rejection is maintained as applied to claims 1-5, 7-9 in paragraph #4 of the previous Office action, and further in view of the following.

Applicant canceled claims 2,3, drawn to cDNA or genomic DNA. However, this cancellation did not make moot the rejection of the remaining claims because the claims, due to the use of open-ended "comprising" language remain to encompass gene sequences, encoding sequences and so forth. None of these products meet the written description provision of 35 USC 112, first paragraph as there is no description of other elements included in DNA, such as non-coding, regulatory regions, etc. The specification provides insufficient written description to support the genus encompassed by the claim. The species specifically disclosed are not representative of the genus because the genus is highly variant.

5. Claims 1,4,5,7-9,18,20-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The rejection is maintained as applied to claims 1-5, 7-9 in paragraph #5 of the previous Office action, and further in view of the following.

Applicant argues that specification describes other sequences that have certain % identity to SEQ ID No. 19, are allelic variants of SEQ ID No. 19, or are hybridizable to SEQ ID No. 19. Examiner maintains that the only species disclosed for the claimed genus is SEQ ID No. 19 itself. There are no other species in possession of applicant that are descriptive of the genus as claimed. No sequence

information indicating what is the necessary common attribute for the polynucleotides encompassed by the claimed genus to be specific to colon cancer cells is present in the specification. With the exception of SEQ ID NO: 19, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

6. (New "new matter" rejection). Claims 1,4,5,7-9,18,20-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 1(d) introduces new matter in amending to read on molecules that have 85% sequence identity to entire length of nucleic molecule comprising nucleic acid molecule comprising sequence SEQ ID No.19. It is not clear what "entire length" is , there is no disclosure in the specification on the meaning and scope of the definition of such product and there is no guidance on how to practice the claimed method with such compounds.

7(new). Claims 1,4,5,7-9,18-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotide SEQ ID No. 19, does not reasonably provide enablement for a nucleic acid molecule having at least 85% identity over entire length to nucleic acid molecule comprising

nucleic acid molecule comprising sequence SEQ ID No.19" (i.e., according to the claim language that follows from reading preamble together with the following components of the claim). As the scope of the genus encompassed by language directed to "85% sequence identity to entire length" is unclear, it is not clear how to make a product that satisfies the % identity limitations. There is no core structure identified for nucleic acids other than SEQ ID No. 19 which is required for such products to be overexpressed in colon cancer tissues (which is now a functional requirement of the claims). Consequently, one skilled in the art would not know how to make product as claimed.

8. (new). Similarly, claims 1,4,5,7-9,18,20-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotide SEQ ID No. 19, does not reasonably provide enablement for a nucleic acid molecules which are allelic variants of SEQ ID No. 19. There is no core structure identified for nucleic acids other than SEQ ID No. 19 which is required for such products to be overexpressed in colon cancer tissues (which is now a functional requirement of the claims). Consequently, one skilled in the art would not know how to make product as claimed.

Claim Rejections - 35 USC § 102

9. Claims 1,4,5,7-9,18-27 are rejected under 35 U.S.C. 102(f). The claims are drawn to polynucleotide SEQ ID NO: 19. As admitted in the applicant's disclosure (specification, p. 116, lines 18-20), in detecting overexpression of said polynucleotide applicants screened proprietary genomic database LIFESEQ Gold commercially available at that time from Incyte Genomics Inc. (see, e.g., press release "Incyte and Vertex Enter Genomic Partnership to Accelerate Drug Discovery in Multi-target Gene Families Using LifeSeq Gold,February 29,2000", http: //www.vpharm.com/ Pressreleases2000/pr022900.html). Consequently, applicants did not themselves invent the claimed subject matter.

The rejection is maintained for the reasons of record set forth for claims 1,3-5 in the previous Office action.

Applicant argues that the referenced genomic database does not employ CLASP algorithm. However, the rejection does not address use of a particular search algorithm. The claims are drawn to a product, not to a method of searching. Applicant did not make any additional steps to make the product which had been already present in the referenced database (the latter is acknowledged by the applicant).

10. Similarly, claims 1,4,5,7-9,18-27 are rejected under 35 U.S.C. 102(a) as being anticipated by genomic database LIFESEQ Gold (see reference in the preceding paragraph). According to applicant's admission (specification, p. 116, lines 18-20),the information about the claimed subject matter was present in said database prior to the invention.

The rejection is maintained for the reasons of record set forth for claims 1,3-5 in the previous Office action, and in view of further arguments presented in the comments to the preceding rejection under 35 U.S.C. 102(f).

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

7/16/04